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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/748,071

12/29/2003

Paul A. Barsanti

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27476

7590

05/31/2007

NOVARTIS VACCINES AND DIAGNOSTICS INC.
CORPORATE INTELLECTUAL PROPERTY R338

P.O. BOX 8097

Emeryville, CA 94662-8097

EXAMINER

SNYDER, STUART

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

05/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/748,071

Applicant(s)

BARSANTI ET AL.

Examiner

Stuart W. Snyder

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1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 4-62 and 64-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the claimed invention of Group I in the reply filed on 3/15/2007 is acknowledged. The traversal is on the ground(s) that the search for both groups would not be unreasonably burdensome. This is not found persuasive because the methods claimed encompass use of the composition of Group I as an adjuvant, immunostimulant or antiviral therapeutic. Each of the methods would require a separate search; in addition, the search required for antiviral activity would require an extremely broad search directed to many and various classes of viruses.

The requirement is still deemed proper and is therefore made FINAL.

2. Applicants are reminded that where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until

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all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues.

See MPEP § 804.01.

3. Applicant's election with traverse of the species formula IX, specifically the compound pyridine-2-carbaldehyde thiosemicarbazone, in the reply filed on 3/15/2007 is acknowledged.

Claims 4-62 and 64-74 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/15/2007.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Gall. The claim is drawn to a vaccine/adjuvant composition comprising, in part, a thiosemicarbazone or derivative thereof serving as the adjuvant. Gall teaches the use of many substances useful as adjuvants to enhance the immunogenicity of vaccines. Gall specifically teaches the use of several thiosemicarbazones that enhanced the immunogenicity of diphtheria toxoid in guinea-pigs (see Table 7, p. 380). Thus, the invention of claim 1 was clearly anticipated by Gall.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-3 and 63 under 35 U.S.C. 103(a) as being unpatentable over Gall in view of Blanz, *et al.* The claims are drawn to a vaccine/adjuvant composition comprising, in part, a thiosemicarbazone or derivative thereof serving as the adjuvant. Gall teaches the uses of many substances useful as adjuvants to enhance the immunogenicity of vaccines. Gall specifically teaches the use of several thiosemicarbazones that enhanced the immunogenicity of diphtheria toxoid in guinea-pigs (see Table 7, p. 380). Gall doesn't teach the use of pyridine-2-carbaldehyde thiosemicarbazone or other members of the class of

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thiosemicarbazones characterized by formula IX of claim 63. Blanz, *et al.*

specifically teaches the use of pyridine-2-carbaldehyde thiosemicarbazone as an anticancer therapeutic.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the vaccine/adjuvant composition of Gall by substituting pyridine-2-carbaldehyde thiosemicarbazone for one of the thiosemicarbazones. The skilled artisan would have been motivated to do so because of the high solubility of pyridine-2-carbaldehyde thiosemicarbazone, as taught by Blanz, *et al.* There would have been a reasonable expectation of success, given the general utility of thiosemicarbazones, as taught by Gall.

Thus, the invention of claims 1-3 and 63 was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

7. No claims are allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart W. Snyder whose telephone number is (571) 272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stuart W Snyder
Examiner
Art Unit 1648

SWS



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